DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 18, 2014

Medtronic, Inc.
Bruce Backlund
Principal Regulatory Affairs Specialist
8200 Coral Sea St. NE
Mounds View, Minnesota 55112

Re: K142673
Trade/Device Name: Bio-Medicus Adult Cannulae and Introducer
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: September 17, 2014
Received: September 19, 2014

Dear Mr. Backlund,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved; OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*

K142673

Device Name

Bio-Medicus Adult Cannula and Introducer

Indications for Use *(Describe)*

These devices are to be used by a trained physician only. Cannulae are used to cannulate vessels, perfuse vessels or organs, and/or connect with accessory extracorporeal equipment. The cannula introducer is intended to facilitate proper insertion and placement of the appropriately-sized cannula within the vessel for cardiopulmonary bypass. The Bio-Medicus™ cannula (18-cm [7.09-in] tip length models) may be used in either the femoral position as an arterial delivery cannula or in the jugular position as a venous return cannula. This product is intended for use up to 6 hours.

Type of Use *(Select one or both, as applicable)*

■ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.•

510(k) Summary of Safety and Effectiveness

Date Prepared: **September 17, 2014**

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establish Registration Number: 2184009

Contact Person: Bruce Backlund
Principal Regulatory Affairs Specialist
Phone: (763) 526-2357
Fax: (763) 367-8361
E-mail:bruce.j.backlund@medtronic.com

Trade Name: Bio-Medicus™ Adult Cannulae and Introducer
Common Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Classification Name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass

Classification: Class II, 21 CFR 870.4210

Product Code: DWF

Name of Predicate Devices: Medtronic Bio-Medicus Femoral Cannula and Introducer (K884129)

Avalon Elite Bi-Caval Dual Lumen Catheter (K081820).

Device Description:
The adult venous and arterial cannulae consist of a polyurethane wirewound body with a multi-port distal tip. The adult venous cannula also has a multi-port body built with stainless steel wirewinding and reinforced baskets. All adult arterial cannulae come with a vented 3/8-in vented connector and all of the adult venous come with a non-vented 3/8-in connector. The overall length of the cannulae is 12.5-in for the adult arterial/jugular and 25.6-in, 26.5-in and 30-in for the adult venous. The Adult cannulae come with a repositionable suture ring that is radiopaque. Insertion depth marks aid in positioning the cannula.

The one-piece non-phthalate PVC introducers included with these cannulae have an elongated taper for dilation over a longer distance.

The Adult Cannula and Introducer package contains a securement clip which can be used near the insertion site for securement of the cannula body which aides in securement as well as an aide for physician organization. The large venous models (Sizes 23 – 29 Fr) also contain a 3/8-in x ½-in tubing adapter with an attached length of 3/8-in tubing to allow connection to a ½-in cardio pulmonary bypass circuit.

Sterile, nonpyrogenic, single use.

Intended Use:

These devices are to be used by a trained physician only. Cannulae are used to cannulate vessels, perfuse vessels or organs, and/or connect with accessory extracorporeal equipment. The cannula introducer is intended to facilitate proper insertion and placement of the appropriately-sized cannula within the vessel for cardiopulmonary bypass. The Bio-Medicus™ cannula (18-cm [7.09-in] tip length models) may be used in either the femoral position as an arterial delivery cannula or in the jugular position as a venous return cannula. This product is intended for use up to 6 hours.

Contraindications:

Alone, the cannula and introducer are not medical treatment devices. The cannula introducer is only to be use with the appropriately-sized Bio-Medicus cannula. These devices are not intended for use, except as indicated above. Do not use if the patient has severe peripheral atherosclerosis or severe arterial dissection.

Comparison to Predicate Devices:

A comparison of the Medtronic Bio-Medicus Adult Arterial and Venous Cannulae to the predicate device indicates the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Similar design features, exceptions include improved transition between the introducer body and cannula tip to increase ease of cannula insertion, venous models include additional drainage opening along the cannula body, reduction in the overall cannula body length within the non-wirewound section and added a radiopaque suture ring.
- Similar materials, exceptions include the introducer material which has changed from Polyurethane to Polyvinyl Chloride (PVC), connector material from Polycarbonate to PVC and hemostasis cap material from Styrene to Silicone.
- Same shelf life

Summary of Performance Data

Pre-clinical bench testing was used to verify the performance characteristics of this device. Animal testing was also completed to establish substantial equivalence with the predicate devices.

The following performance tests were conducted:

- Blood Trauma Testing
- Sterilization Testing
- Biocompatibility Testing
- Packaging Testing
- Pressure Drop Testing
- Cannula Life Testing
- Cannula and Introducer Testing
- Cannula Testing
- Introducer Testing
- Securement Clip Testing

Conclusion:

The primary predicate device, Bio-Medicus™ Percutaneous Cannula & Introducer Set, was used to compare the fundamental technological characteristics of the proposed Bio-Medicus Adult Cannula and Introducer. When comparative testing was completed, the proposed Bio-Medicus Adult Cannulae and Introducer performed as well or better than the legally marketed devices.

The data included in this submission is sufficient to provide reasonable assurance that the proposed Bio-Medicus Adult Arterial and Venous Cannulae are substantially equivalent to the legally marketed predicate devices, Bio-Medicus Percutaneous Cannula and Introducer Set (K884129) and Avalon Elite Bi-Caval Dual Lumen Catheter (K081820).